Reply to Office Action of 27 February 2004

This listing of claims will replace all prior versions and listings of claims in the Application:

Listing of Claims:

Claim 1 (presently amended): A method for alleviating a disease state resulting from a microbial

infection affecting sub-dermal musculoskeletal soft tissue in a predetermined area of the body,

said method comprising the steps of:

determining a localized area of a patient's body in which affected

musculoskeletal soft tissue is located;

providing a treatment composition comprising, in combination:

(i) a selected macrolide antibiotic; and

(ii) a selected mobilizing agent in an amount sufficient to enable said

macrolide antibiotic to penetrate into said sub-dermal musculoskeletal soft tissue;

and

applying said treatment composition to said predetermined localized area of

[[the]] said patient's body so that said macrolide antibiotic penetrates said sub-

dermal affected musculoskeletal soft tissue so as to reach said microbial infection

therein.

Claim 2 (presently amended): The method of claim 1, wherein the step of applying said treatment

compound comprises:

applying said treatment composition topically to a skin area overlying said sub-

dermal musculoskeletal soft tissue in said predetermined area of the body.

Claim 3 (presently amended): The method of claim 1, wherein the step of applying said treatment

composition comprises:

applying said treatment composition by hypodermic injection into said sub-

dermal musculoskeletal soft tissue in said area of the body.

Claim 4 (previously cancelled)

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Claim 5 (previously cancelled):

Claim 6 (previously cancelled):

Claim 7 (previously cancelled):

Claim 8 (original): The method of claim 1, wherein said treatment composition further comprises:

a penetration enhancing adjuvant.

Claim 9 (original): The method of claim 8, wherein said penetration enhancing adjuvant comprises d-limonene.

Claim 10 (presently amended): A treatment composition for alleviating a disease state resulting from a microbial infection affecting sub-dermal musculoskeletal soft tissue in a predetermined area of the body, said treatment composition comprising:

- (i) a selected macrolide antibiotic; and
- (ii) a selected mobilizing agent comprising a selected organic gel compound in an amount sufficient to enable said macrolide antibiotic to penetrate into said sub-dermal musculoskeletal soft tissue so as to reach said microbial infection therein when said composition is applied to said predetermined area of the body.

Claim 11 (previously cancelled)

Claim 12 (previously amended): The treatment composition of claim 10, wherein said macrolide antibiotic composition is selected from the group consisting of azithromycin, erythromycin and roxithromycin

Claim 13 (original): The treatment compound of claim 12, wherein said macrolide antibiotic compound is azithromycin.

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Claim 14 (presently amended): The treatment composition of claim 12, wherein said mobilizing agent organic gel compound comprises a selected organogel compound.

Claim 15 (presently amended): The treatment composition of claim [[13]] 14, wherein said organogel compound is PLO gel.

Claim 16 (presently amended): The treatment composition of claim 10, further comprising:

a selected penetration enhancing adjuvant for increasing penetration of said sub-dermal musculoskeletal soft tissue in said predetermined area of the body.

Claim 17 (original): The treatment composition of claim 16, wherein said penetration enhancing adjuvant comprises d-limonene.

Claim 18 (original): A treatment composition for alleviating pain and inflammation resulting from a microbial infection affecting sub-dermal musculoskeletal tissue in a predetermined area of the body, said treatment composition comprising:

- (i) a macrolide antibiotic compound selected from the group consisting of azithromycin, erythromycin and roxithromycin; and
- (ii) PLO gel in an amount sufficient to enable said macrolide antibiotic compound to penetrate into said sub-dermal soft tissue so as to reach said microbial infection therein when said composition is applied topically to said predetermined area of the body.

Claim 19 (original): The treatment composition of claim 18, wherein said macrolide antibiotic compound is present in said composition in an amount in the range from about 50 mg/cc of PLO gel to about 3 gm/cc of PLO gel.

Claim 20 (original): The treatment composition of claim 19, wherein said macrolide antibiotic compound is azithromycin.

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Claim 21 (original): The treatment composition of claim 20, wherein said azithromycin is present in said composition in an amount of about 250 mg/cc of PLO gel.

Claim 22 (original): The treatment composition of claim 18, further comprising:

a selected penetration enhancing adjuvant for increasing penetration of said macrolide antibiotic compound into said sub-dermal soft tissue.

Claim 23 (original): The treatment composition of claim 22, wherein said penetration enhancing adjuvant comprises d-limonene.

Claim 24 (previously added): A method of alleviating a disease state resulting from a microbial infection affecting sub-dermal soft tissue in a predetermined area of the body, said method comprising the steps of:

Providing a treatment composition comprising, in combination:

- (i) a macrolide antibiotic macrolide antibiotic selected from the group consisting of azithromycin, erythromycin and roxithromycin; and
- (ii) PLO gel in an amount sufficient to enable said macrolide antibiotic to penetrate into said sub-dermal soft tissue; and applying said treatment composition to said predetermined area of the body so that said macrolide antibiotic penetrates said sub-dermal soft tissues so as to reach said microbial infection therein.

Claim 25 (previously added): The method of claim 24, wherein said treatment composition further comprises:

a penetration enhancing adjuvant.

Claim 26 (previously added): The method of claim 25, wherein said penetration enhancing adjuvant comprises d-limonene.

Claim 27 (previously added): A method for alleviating a disease state resulting from a microbial infection affecting sub-dermal soft tissue in a predetermined area of the body, said method comprising the steps of:

providing a treatment composition comprising, in combination:

- (i) a selected macrolide antibiotic;
- (ii) a selected mobilizing agent in an amount sufficient to enable said macrolide antibiotic to penetrate into said sub-dermal soft tissue; and
- (iii) a penetration enhancing adjuvant comprising limonene; and applying said treatment composition to said predetermined area of the body so that said macrolide antibiotic penetrates said sub-dermal soft tissue so as to reach said microbial infection therein.

Claim 28 (previously added): The method of claim 27, wherein the step of applying said treatment compound comprises:

applying said treatment composition topically to a skin area overlying said subdermal soft tissue in said predetermined area of the body.

Claim 29 (previously added): The method of claim 27, wherein the step of applying said treatment composition comprises:

applying said treatment composition by injection into said sub-dermal soft tissue in said area of the body.

Claim 30 (previously added): The method of claim 27, wherein the step of providing said treatment composition comprises:

selecting said macrolide antibiotic from the group consisting of azithromycin, erythromycin and roxithromycin.

Claim 31 (previously added): The method of claim 30, wherein said mobilizing agent comprises a gel compound.

Claim 32 (previously added): The method of claim 31, wherein said gel compound is PLO gel.

Claim 33 (presently amended): A treatment composition for alleviating a disease state resulting from a microbial infection affecting sub-dermal musculoskeletal soft tissue in a predetermined area of the body, said treatment composition comprising:

- (i) azithromycin; and
- (ii) a selected mobilizing agent <u>comprising a selected organic gel compound</u> in an amount sufficient to enable said macrolide antibiotic to penetrate into said [[sub-dermal]] soft tissue so as to reach said microbial infection therein when said composition is applied to said predetermined area of the body.

Claim 34 (presently amended): The treatment composition of claim 33, wherein said mobilizing agent organic gel compound comprises a selected organogel compound.

Claim 35 (previously added): The treatment composition of claim 34, wherein said organogel compound is PLO gel.

Claim 36 (previously added): The treatment composition of claim 33, further comprising:

a selected penetration enhancing adjuvant for increasing penetration of said subdermal soft tissue in said predetermined area of the body.

Claim 37 (previously added): The treatment composition of claim 36, wherein said penetration enhancing adjuvant comprises d-limonene.

Claim 38 (previously added): A treatment composition for alleviating a disease state resulting from a microbial infection affecting sub-dermal soft tissue in a predetermined area of the body, said treatment composition comprising:

- (i) a selected macrolide antibiotic;
- (ii) a selected mobilizing agent in an amount sufficient to enable said macrolide antibiotic to penetrate into said sub-dermal soft tissue so as to reach said microbial infection therein when said composition is applied to said predetermined area of the body; and

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(iii) a selected penetration enhancing adjuvant for increasing penetration of

said sub-dermal soft tissue in said predetermined area of the body, said penetration

enhancing adjuvant comprising d-limonene.

Claim 39 (previously added): The treatment composition of claim 38, wherein said macrolide

antibiotic composition is selected from the group consisting of azithromycin, erythromycin and

roxithromycin.

Claim 40 (presently amended): The treatment eompound composition of claim 39, wherein

said macrolide antibiotic compound is azithromycin.

Claim 41 (previously added): The treatment composition of claim 39, wherein said mobilizing

agent comprises a selected organogel compound.

Claim 42 (presently amended):

The treatment composition of claim [40] 41, wherein said

organogel compound is PLO gel.